REMARKS

Claims 1 – 2, 4 – 12, and 17 are pending in this application with claims 1, 2, and 17 being amended by this response to more clearly define the invention. Claims 3, 13 – 16, and 18 – 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention. Support for the amendments to the claims may be found throughout the present specification and, more specifically, on page 13, line 24 - page 14, line 11 and elsewhere. Applicant respectfully submits that no new matter has been added by these amendments.

Rejection of claims 1-2 and 4-12 under 35 U.S.C. 101

Claims 1-2 and 4-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory matter.

Applicant respectfully disagrees with the assertion that the claimed invention is not directed towards statutory subject matter. The Office Action cites a single clause from the Application: "The processor 126 may be implemented in software and/or hardware" and reads that passage as implying that the processors of claim 1 recite "software and/or software embodiments" (Office Action page 3, lines 1 - 16). Applicant respectfully submits that, in reading the above sentence as only implying software is unreasonable. The specification clearly contemplates multiple combinations of elements in any form of hardware, software or a combination thereof. The interpretation made by the Rejection artificially and unduly limits the scope of Applicants invention. Specifically, independent claim 1 includes a "generator for generating," a "data processor using said communication interface for filtering," and an "output processor for converting". These encompass hardware elements as contemplated in the present specification and the interpretation that the system is software per se is unreasonable and unfounded. Therefore, the elements of the claim comprise a machine or manufacture as specified in 35 U.S.C. 101.

Specifically, the Application states on page 5, lines 18 – 19, regarding Figure 1, "The processor 126 may be implemented in software and/or hardware **and operates responsive to the software program stored in the memory** 128". The processor 126 constitutes a component of the server 104. The Application earlier stated regarding the processor:

> The server 104 further includes a processor 126, a memory 128, a memory 130, and a data format conversion processor . . . 132 . . . . The server 108 also includes a processor, a first memory, a second memory, and a data format conversion processor, and is constructed and operates in a similar manner to the server 104. (Application page 5, lines 10 – 14)

and prior to that, regarding the role of the server in the system:

> The system 100 generally includes . . . a server 104, a client 106, a server 108, and a client 110. Together, the server 104 and the client 106 preferably form a client / server computer architecture . . . as is well known in the art. Alternatively, the server 104 and the client 106 may form an integral computer architecture . . . as is well known in the art. The server 108 and the client 110 are also designed in an analogous preferred and alternate manner . . . (Application page 3, line 31 – page 4 line 4)

Thus, it is clear in the specification that, as is well known in the art, a "processor" that "operates responsive to" a program as the Application states includes hardware elements to accomplish its operation. By selecting only the first verb phrase in the cited sentence, while ignoring the second verb phrase in the same sentence that specifies that "[t]he processor . . . operates," the Office Action misconstrues the statement.

The Application clearly intends that the term "processor" in its use in the claims be given its conventional meaning in the art, i.e., the logic circuitry that extracts, decodes, and executes instructions to cause a computer to operate on data. The processor may exist solely as hardware or as a combination of hardware and software, wherein the software code, executed on a general purpose computer processor, conditions it to perform the specific functions identified in claim 1, as is well known in the art. Therefore, the processor and generator of claim 1 constitute a machine or manufacture that produces a useful, concrete and tangible result from the information operating thereon. The Examiner's interpretation is not a valid reading by one of ordinary skill in the art, who is aware that a "processor" that "operates responsive to" a program must be realized by functional elements that satisfy the requirements of 35 U.S.C. 101 for a machine or manufacture.

Claims 2 and 4 – 12 are dependent on claim 1 and are considered patentable for the reasons set forth above regarding claim 1.

Applicant respectfully submits that, as indicated in the present specification, the claimed combination includes a generator, data processor, output processor, and communication interface are statutory subject matter under 35 U.S.C. 101. Thus, Applicant respectfully submits that claims 1, 2, and 4 – 12 are in compliance with 35 U.S.C. 101; and withdrawal of their rejection under 35 U.S.C. 101 is respectfully requested.

Rejection of claims 1, 4-7, 9-10 and 17 under 35 U.S.C. 102(b)

Claims 1, 4-7, 9-10 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Crawford (U.S. Patent No. 5,331,549).

Amended independent claim 1 provides a distribution system for patient medical parameter. A generator for generating data representing at least one displayed user interface image enables a user to enter configuration data which supports user selection of a plurality of patient parameter types, an associated patient, and associated predetermined filtering criteria.

The filtering criteria include a time interval between acquisition of patient medical parameter values from at least one patient monitoring device of the plurality of patient parameter types of the user selected associated patient. A communication interface for acquiring patient parameters in a first data format from patient monitoring devices is attached to a plurality of different patients. The patient parameters are acquired at a user selectable acquisition receiving interval in response to the configuration data. A data processor uses the communication interface for filtering acquired patient parameters for an individual patient in response to the configuration data to identify patient parameters meeting predetermined filtering criteria determinable by a user for an individual parameter type and an individual patient, and for excluding other patient parameters. An output processor converts the filtered identified parameters in the first data format to a different second data format and uses the communication interface for output communication of the filtered identified patient parameters together with a parameter time and date of acquisition indication in the second data format

The Office Action rejects claim 1 as anticipated by Crawford, citing the statement in Crawford that lists, among "[t]he operational features which are critical to why this system is an improvement over anything presently known and in particular why it provides a meaningful monitoring of a large number of patients, . . . The selection of a limited number of vital signs (six in particular) (Crawford col. 7 lines 37 – 43). In fact, the cited passage teaches away from "enabling a user to enter configuration data supporting user selection of (i) a plurality of patient parameter types" as recited in claim 1 of the present system. Rather, Crawford teaches the advantages of a system that enables acquisition of only six parameters. "By limiting the vital signs monitored to six, it becomes possible and feasible to monitor a large number of sites. Thus the system is particularly adapted to the general hospital situation more than to the intensive care unit situation (ICU). . . . The six vital signs themselves are meaningful enough for most patients, and the number of patients who require this level of monitoring is a significant percentage of those occupying hospital rooms, a number many times greater than even the largest ICU's can handle" (Crawford col. 7 lines 15-36).

In Crawford, if one or more of the six parameters provided by the system is not being monitored and not available, then fewer than six parameters are displayed in window 72. The "selection" on the part of the user is limited to choosing to monitor or not to monitor some of the six parameters for the patient. There is no contemplation of, or user ability for, selecting any additional or different signals or data in the system. Thus, for example, Crawford states "Notification States **1** through **8** are only for those vital signs being monitored. If a vital sign is not selected on the window 72, then that sign will appear solid purple (Notification State **9**) and the other Notification States will be provided in response to only those signs being monitored" (Crawford col. 9, lines 21-26). In fact, Crawford explicitly rejects the acquisition of other types of patient parameters, stating "[t]he transmission and analysis of wave forms is

what requires hundreds of times more processing power" and "[t]he six vital signs themselves are meaningful enough for most patients" (Crawford, col. 7 lines 27 – 33).

In contrast, the claimed system advantageously enables and is intended to enable monitoring of a significant number of parameters. "Presently, there are up to three hundred twenty potential patient vital signs that can be monitored" (Application page 6, lines 3 – 4). By teaching standardization on only the 6 parameters, Crawford teaches away from use of "at least one displayed user interface image enabling a user to enter configuration data supporting user selection of, (i) a plurality of patient parameter types, (ii) an associated patient, and (iii) associated predetermined filtering criteria including a time interval between acquisition of patient medical parameter values from at least one patient monitoring device of said plurality of patient parameter types of said user selected associated patient" as recited in claim 1 of the present arrangement. Unlike the claimed invention, Crawford puts a cap on the number of parameters monitored and does so for a specific purpose. Any deviation therefrom would render the Crawford system unusable and inoperable.

Crawford also fails to disclose or suggest "user selection of, **a time interval between acquisition of patient medical parameter values** from at least one patient monitoring device of said plurality of patient parameter types of said user selected associated patient" as further recited in claim 1. The only acquisition contemplated in Crawford is related to patient disconnection from a monitoring device, not to selection of acquisition time intervals. In Crawford, the only options for data acquisition are continuous - patient must always be connected to monitor, is not ambulatory," semi-continuous - "patient may disconnect from time to time, may be ambulatory, e.g. someone in for overnight observation," or sporadic - "patient has signs checked by hooking up to a monitor from time to time, e.g. an outpatient" (Crawford col. 12 lines 5 – 23). When the patient is connected to the monitoring device, monitoring is continuous and a user does not have an ability to specify parameters to control the frequency of data acquisition. This is completely different from the present claimed system, in which the user interface enables "a user to enter configuration data supporting user selection of . . . filtering criteria including a time interval between acquisition of patient medical parameter values" as recited in claim 1. In view of the above remarks and amendments to claim 1, withdrawal of the rejection is respectfully requested.

Claim 4 is dependent on claim 1 and is considered patentable for the reasons presented above with regard to claim 1. Claim 4 is also considered patentable because, Crawford nowhere discloses or suggests "wherein said data processor acquires patient parameters at a user selectable acquisition interval," or that the selection be made of "an individual parameter type and an individual patient" as recited in claim 4. Specifically, since Crawford merely describes that patient status can be classified as one of Level 1 (sporadic monitoring), Level 2 (semi-continuous monitoring), or Level 3 (continuous monitoring),

Crawford neither discloses nor suggests an "acquisition receiving interval selectable by a user for an individual parameter type" as recited in claim 4. Unlike the present system, Crawford describes an interface for data acquisition structured around a DDE (Dynamic Data Exchange) driver, which transmits only changes in data, rather than transmission at a selectable interval frequency.

The Office Action asserts that Crawford teaches selecting a subset of the data for a specific patient, but such selection merely of monitoring or not monitoring of one of the six available vital signs in Crawford is clearly **not** equivalent to the acquisition of patient parameters "at a user selectable **acquisition receiving interval** selectable by a user for an individual parameter type and an individual patient" as recited in claim 4. Moreover, claim 4 clearly provides for making selections for "an individual parameter type **and** an individual patient," requiring that **both** types of selection be supported. These features are not contemplated by Crawford. Consequently, withdrawal of the rejection of claim 4 is respectfully requested.

Claims 5 and 6 are dependent on claim 1 and are considered patentable for the reasons presented earlier with regard to claim 1. Consequently, withdrawal of the rejection of claims 5 and 6 is respectfully requested.

Claim 7 is dependent on claim 1 and is considered patentable for the reasons presented above with regard to claim 1. Claim 7 is further considered patentable because Crawford nowhere discloses or suggests "a displayed user interface image" to allow selection of a storage file for data "in response to user storage file type selection command" as recited in claim 7. Crawford teaches only the presentation to the user of a choice of monitoring or not monitoring a given one of the six vital signs. That single decision drives every action of Crawford except for the alarm limits settings. The passage cited in the Office Action merely describes the ability to select which of the six monitored vital signs being monitored and stored **to display** currently. In Crawford, there is no option or selection provided for storage of the data; storage is automatic. This is in no way equivalent to "a displayed user interface image" to allow "storage file type selection" by a user as provided in claim 7. Consequently, withdrawal of the rejection of claim 7 is respectfully requested.

Claims 9 and 10 are dependent on claim 1 and are considered patentable for the reasons presented above with regard to claim 1.

Amended independent claim 17 provides a method for distributing patient medical parameters. Data is generated representing at least one displayed user interface image enabling a user to enter configuration data. The configuration data supports user selection of,

a plurality of patient parameter types, an associated patient, and associated predetermined filtering criteria. The filtering criteria include a time interval between acquisition of patient medical parameter values from at least one patient monitoring device of the plurality of patient parameter types of the user selected associated patient. Patient parameters are acquired in a first data format from patient monitoring devices attached to a plurality of different patients. The patient parameters are acquired at a user selectable acquisition receiving interval in response to the configuration data. Acquired patient parameters are filtered for an individual patient in response to the configuration data to identify patient parameters meeting predetermined filtering criteria determinable by a user. The filtering criteria are for an individual parameter type and an individual patient, and for excluding other patient parameters. The filtered identified parameters in the first data format are converted to one or more different second data formats including Health Level Seven (HL7) compatible data format. The communication interface is used for output communication of the filtered identified patient parameters together with a parameter time and date of acquisition indication in the second data format.

Claim 17 has features similar to those of claim 1 and is considered patentable for the reasons presented earlier with regard to claim 1. Claim 17 is further considered patentable because the use of Health Level 7 compatible data format as provided in claim 17 has a distinct advantage recognized by inventors: because of the structure protocol format of HL7 there is advantageously no need for configuration and use of fixed mapping files as were required in prior art (Application page 20 lines 30 – 34). This advantageous feature is nowhere contemplated in Crawford. Crawford is completely silent on the formats to be used for the output to any storage files of patient parameters acquired by its system. Beyond the statement that "Patient data is stored at regular intervals" (Crawford col. 2 lines 57 – 58), Crawford does not contemplate conversion of the data acquired from patient monitoring devices, except to describe displaying the acquired data in a GUI display. Crawford describes only the provision of data from the "central server" to a "local workstation PC" for display (Crawford Figure 1 and col. 3 line 61 – col. 4 line 4). In contrast, claim 17 of the present arrangement recites "acquiring patient parameters in a first data format from patient monitoring devices . . . and converting said filtered identified parameters in said first data format to one or more different second data formats including Health Level 7 compatible data format; and using said communication interface for output communication of said filtered identified patient parameters together with a parameter date and time of acquisition indication in said second data format".

In view of the above remarks and amendments to the claims, Applicant respectfully submits that Crawford fails to provide enabling disclosure that anticipates each feature claims in independent claims 1 and 17. As claims 4 – 7, 9 and 10 are dependent on claim 1, Applicant further respectfully submits that these claims are similarly not anticipated by

Crawford. Consequently, withdrawal of the rejection of claims 1, 4 – 7, 9, 10 and 17 is respectfully requested.

Rejection of claim 2 under 35 U.S.C. 103(a)

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford (U.S. Patent No. 5,331,549) in view of Official Notice.

Amended dependent claim 2 further provides a system wherein the at least one displayed user interface image enables a user to enter configuration data supporting user selection of a time interval over which a patient parameter type of the user selected associated patient is averaged. Also, the second data format is a Health Level Seven (HL7) compatible data format, and the communication interface automatically selects at least one communication protocol and destination port, in processing the filtered identified parameters in the first data format for output communication.

The Office Action asserts that claim 2 would have been obvious in view of Crawford, taking Official Notice that use of the Health Level 7 data format is old and well established in the art of health care information systems. Crawford, fails to contemplate use of such a data format in the claimed manner, and instead, as indicated in the cited passage teaches that, the same driver (DDE driver) that receives the data from the monitoring devices "sends local digitized patient data to the monitoring program in the CPU 17 of the central server **and to local work stations 24 and remote work stations**" (Crawford, col. 3 lines 60 – 68). Crawford fails to disclose or suggest data conversion to accommodate use or storage of the data before sending it to other locations. This is wholly unlike and fundamentally different from the present claimed system, which includes "an output processor for converting said filtered identified parameters in said first data format to a different second data format" as recited in claim 1, wherein "said second data format is a Health Level Seven (HL7) compatible data format" as recited in claim 2. Further, the Application notes that, because of the structure protocol format of HL7, there is advantageously no need for configuration and use of fixed mapping files as were required in prior art (Application page 20 lines 30 – 34). This advantageous feature is nowhere contemplated in Crawford.

Moreover, Crawford nowhere discloses or suggests wherein "said at least one displayed user interface image enables a user to enter configuration data supporting user selection of a time interval over which a patient parameter type of said user selected associated patient is averaged" as recited in amended claim 2. Crawford contemplates no averaging of patient parameters, and no user control over filtered identified parameters beyond selecting to display the trend of one of the six monitored vital signs over the past twenty four hours. Consequently, withdrawal of the rejection of claim 2 is respectfully requested.

Rejection of claim 8 under 35 U.S.C. 103(a)

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford (U.S. Patent No. 5,331,549) in view of Matthews (U.S. Patent No. 5,860,124).

Dependent claim 8 further provides a system wherein the output processor communicates data to the storage file for at least one of overwriting of existing data in the storage file and adding to existing data in the storage file in response to user command.

Claim 8 is dependent on claim 1 and is considered patentable for the reasons presented earlier with regard to claim 1. Claim 8 is further considered patentable because neither Crawford nor Matthews, separately or in combination, provides an "output processor" that " communicates data to said storage file for at least one of overwriting of existing data in said storage file and adding to existing data in said storage file in response to user command" as recited in claim 8. Moreover, as discussed above, Matthews (with Crawford) does not disclose or suggest a "displayed user interface image enabling a user to enter configuration data supporting selection of, (i) a plurality of patient parameter types, (ii) an associated patient, and (iii) associated predetermined filtering criteria including a time interval between acquisition of patient medical parameter values from at least one patient monitoring device of said plurality of patient parameter types of said user selected associated patient" as recited in claim 1.

As discussed earlier, Crawford describes a system for monitoring a limited set of vital signs for a plurality of patients. The system includes a supervisory screen display and a driver that sends local digitized patient data to local and remote work stations (Crawford Abstract). The system also describes a limited user capability to modify certain parameters regarding a particular patient (Crawford col. 8 lines 17 – 20). One option in Crawford is for the user to select the "trends window" to display one of the patient's vital signs as a time line, with an optional interface to enter a start and end date for the display (Crawford col. 8 lines 51 – 62). However, the user selection is only whether or not to display the data; Crawford nowhere provides a user command to control communication of data **"to said storage file"** as recited in claim 8.

Matthews describes a method for performing a continuous overwrite of a file in non-volatile memory, to accommodate the objective of continuously updating a file of a limited size as new data is received (Matthews Abstract). However, the method described in Matthews is a general use overwrite method and fails to provide enabling disclosure of the claimed overwrite function. However, Matthews nowhere discloses or suggests the use of a user command to control the operation of such a method. Matthews only describes the algorithm for allocating a spare sector, mapping logical and physical sectors, and determining which sector is the next to be overwritten. There is no discussion of any user interface or user command to control the operation of the algorithm.

Including the teaching of Matthews in the system of Crawford does provide a system in which continuously updated data for a particular vital sign is stored on a file of limited size, but that system still does not communicate "data to said storage file . . . **in response to user command**" as recited in claim 8. Matthews fails to describe a user interface, and Crawford contemplates a user command only to **display** the data, not to control whether or how particular data is written to a storage file. The provision of a user interface to allow control over the way in which monitoring data is stored is a significant advantage of the present system. Consequently, withdrawal of the rejection of claim 8 is respectfully requested.

Rejection of claims 11-12 under 35 U.S.C. 103(a)

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford (U.S. Patent No. 5,331,549) in view of Teller (U.S. Patent No. 6,605,038).

Claim 11 is dependent on claim 1 and is considered patentable for the reasons presented above with respect to claim 1. Claim 11 is further considered patentable because Teller (with Crawford) fail to disclose or suggest a "data processor" that "adaptively averages values of an acquired patient parameter for an individual patient". Additionally, Teller (with Crawford) fail to disclose or suggest "at least one displayed user interface image enabling a user to enter configuration data supporting user selection of, (i) a plurality of patient parameter types, (ii) an associated patient, and (iii) associated predetermined filtering criteria including a time interval between acquisition of patient medical parameter values from at least one patient monitoring device of said plurality of patient parameter types of said user selected associated patient" as recited in claim 1.

The Office Action concedes that Crawford fails to teach a system which "adaptively averages," but asserts that all of the other features of claim 11 are disclosed or suggested by Crawford and that Teller provides a system that "adaptively averages" a heart rate over a period of time. However, unlike the claimed system, Teller describes a system for detecting, monitoring and reporting human physiological information (Teller col. 1 lines 55 – 56). The system is designed to support individuals seeking a healthier lifestyle. It includes a sensor device "adapted to be placed in contact with an individual's upper arm" that includes at least one of an accelerometer, a galvanic skin response detector, and a heat flux sensor (Teller col. 1 lines 56 – 58). The sensor device communicates with a central monitoring unit that retrievably stores the data it receives and generates. The central monitoring unit also generates analytical status data and, optionally, one or more web pages containing received or derived data (Teller col. 2 lines 3 – 24). Teller makes many general and encompassing statements, such as "Sensor device 10 includes one or more sensors, which are adapted to

generate signals in response to physiological characteristics of an individual, and a microprocessor" (Teller, col. 4 lines 5 – 8). The passage cited by the Examiner states: "for example, the microprocessor [of the sensor] can be programmed to calculate an average, minimum or maximum heart rate or respiration rate over a defined period of time, such as ten minutes" (Teller col. 5 lines 33 – 35). Although the Office Action asserts that applying the teachings of Teller to Crawford would have been obvious to one skilled in the art, Applicant respectfully disagrees. Combining the two systems would not be obvious, because they have wholly unrelated objectives that are accomplished using fundamentally different mechanisms. Crawford is designed to support the basic monitoring of as many patients as possible, so that the system may be efficiently installed in a hospital. In contrast, Teller is designed to provide as comprehensive as possible a set of parameters for an individual user who is monitoring his own health and lifestyle. Indeed, Crawford explicitly rejects the monitoring of any vital signs beyond the six specified parameters of systolic, diastolic, pulse, respiration, temperature, and oxygen saturation; while Teller requires that its sensor include at least one of an accelerometer, a galvanic skin response detector, and a heat flux sensor. Thus, the limitations strictly set in the Crawford system would not allow for combination with the Teller system as it would render Crawford inoperable and unable to operate in the intended manner.

Even if the system of Teller and Crawford could be operably combined, the combination of Teller with Crawford would not disclose or suggest "at least one displayed user interface image enabling a user to enter configuration data supporting user selection of, (i) a plurality of patient parameter types, . . . and (iii) associated predetermined filtering criteria including a time interval between acquisition of patient medical parameter values from at least one patient monitoring device" as recited in claim 1, upon which claim 11 depends. Consequently, it is respectfully requested that the rejection of claim 11 be withdrawn.

Claim 12 is dependent on claim 11 and is considered patentable for the reasons presented above with respect to claims 1 and 11. Claim 12 is further considered patentable because Teller (with Crawford) neither discloses nor suggest that the "data processor adaptively averages values of an acquired patient parameter for an individual patient in response to user selection of a desired number of values over which the parameter is to be averaged". The Examiner cites Crawford teaching the selection of the period to display historical trend data, but the selection in Crawford only enables the user to select **whether to display** a trend line covering the past twenty four hours, or some longer period, by entering a start date for the trend line display. This selection of how much data **to display** is completely different from the "user selection of a desired **number of values over which said parameter is to be averaged**" as recited in claim 12, which enables smoothing data over some multiple of readings to minimize the effects of transient anomalies from a monitoring device. The two

selections do not perform the same function or produce the same result, and are in no way equivalent. Consequently, Applicant respectfully requests withdrawal of the rejection of claim 12.

Having fully addressed the Examiner's rejections, it is believed that, in view of the preceding amendments and remarks, this application stands in condition for allowance. Accordingly then, reconsideration and allowance are respectfully solicited. If, however, the Examiner is of the opinion that such action cannot be taken, the Examiner is invited to contact the applicant's attorney at the phone number below, so that a mutually convenient date and time for a telephonic interview may be scheduled.

Respectfully submitted,
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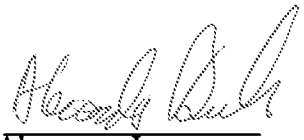
By: 
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